UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

- -x

IN RE GPC BIOTECH AG SECURITIES LITIGATION

OPINION

07 Civ. 06728 (DC)

- -x

APPEARANCES:

LABATON SUCHAROW LLP
By: Joel H. Bernstein, Esq.
140 Broadway
New York, New York 10005
Attorneys for Lead Plaintiff Axxion S.A. Luxemburg

ABBEY SPANIER RODD & ABRAMS, LLP
By: Nancy Kaboolian, Esq.
Richard B. Margolies, Esq.
212 E. 39th Street
New York, New York 10016
Attorneys for Plaintiff Agamemnon Chua

MORGAN, LEWIS & BOCKIUS LLP
By: Bernard J. Garbutt III, Esq.
101 Park Avenue
New York, New York 10178
Marc J. Sonnenfeld, Esq.
William P. Quinn, Jr., Esq.
Karen Pieslak Pohlmann, Esq.
1701 Market Street
Philadelphia, Pennsylvania 19103
Attorneys for Defendants GPC Biotech AG, Bernd R. Seizinger, Mirko Scherer, Elmar Maier, and Sebastian Meier-Ewert

CHIN, District Judge

In this securities fraud case, plaintiffs allege that defendants made material misrepresentations and omissions concerning the Food and Drug Administration ("FDA") "fast track" approval process of an experimental anti-cancer drug, Satraplatin. According to plaintiffs, the misrepresentations and

omissions artificially inflated the stock price of the pharmaceutical company. Upon news that the FDA did not have experience with the "endpoint" used for Satraplatin in clinical trials and, ultimately, that fast track approval was not granted, the stock price dropped dramatically, losing over fifty percent of its value. Lead plaintiff Axxion S.A. Luxemburg ("Axxion") and plaintiff Agamemnon Chua ("Chua"), on behalf of themselves and all other persons or entities, except for defendants, who purchased GPC securities (the "class") from December 5, 2005 through July 14, 2007 (the "class period"), bring a consolidated class action complaint (the "complaint") against defendants GPC Biotech AG ("GPC") and Bernd R. Seizinger, Mirko Scherer, Elmar Maier, and Sebastian Meier-Ewert (the "Individual Defendants"). Plaintiffs seek damages for violations of Sections 10(b), 20(a), and 20A of the Securities and Exchange Act of 1934, and Rule 10b-5 promulgated thereunder. Defendants move pursuant to Fed. R. Civ. P. 12(b)(6) and 9(b) and the Private Securities Litigation Reform Act of 1995 (the "PSLRA") to dismiss the complaint. For the following reasons, defendants' motion is denied.

BACKGROUND

For purpose of this motion, the facts in the complaint are assumed to be true and are construed in the light most favorable to plaintiffs.

A. The Parties

Axxion is a Luxemburg investment firm managing assets totaling approximately 1.7 billion euros. (Compl. ¶ 28). Axxion sues on behalf of Akrobat Fund-Value, an investment fund that

Axxion manages, which purchased GPC common stock during the class period. (Id.). Chua is a United States citizen who also purchased GPC shares during the period in question. (Id. ¶ 29).

GPC is a publicly traded biopharmaceutical research and development company. (Id. ¶ 2). It is headquartered in Munich, Germany with a wholly-owned United States subsidiary in Princeton, New Jersey. (Id.). GPC's sponsored American Depository Receipts evidencing American Depository Shares are registered and traded on the NASDAQ Global Market. (Id. ¶ 31). The company's focus is on "discovering, developing, and commercializing new anticancer drugs." (Id. ¶ 2).

Seizinger has served as GPC's Chief Executive Officer since 1998. (Id. ¶ 32). Scherer was GPC's Chief Financial Officer until December 4, 2007; Maier was GPC Senior Vice President, Business Development and Chief Operating Officer until February 25, 2008; and Meier-Ewert was, until February 25, 2008, GPC's Senior Vice President and Chief Scientific Officer. (Id. ¶¶ 33-35). Seizinger, Scherer, Maier, and Ewert were members of GPC's Management Board during the class period. (Id. ¶ 36).

B. Satraplatin and the FDA Approval Process

In 2002, GPC obtained an exclusive license to develop the experimental drug, Satraplatin. (Id. ¶ 3). Satraplatin was intended for use as a chemotherapy treatment. (Id.). GPC hoped that Satraplatin would prove effective at combating prostate cancer. (Id. ¶ 47). Satraplatin, unlike other cancer drugs, was to be administered orally, thus providing the added advantage of allowing patients to take it at home. (Id.).

Before GPC could market and distribute Satraplatin in the United States and Europe, it was required to perform advanced clinical testing, demonstrate the drug's efficacy, and receive full regulatory approval by the FDA and European regulatory authorities. (Id. ¶ 3). The process was under serious time constraints, as the two U.S. patents for Satraplatin were set to expire in 2008 and 2010 and the patents in most other countries in 2009. (Id. ¶ 4). To expedite the approval process, GPC sought "fast track designation" by the FDA of its New Drug Application ("NDA") for Satraplatin and additional funding from private investors. (Id. ¶¶ 6, 51).

In July 2003, representatives of GPC met with the FDA to discuss plans to initiate human trials on patients suffering from prostate cancer, known internally as the "SPARC" trial. (Id. ¶¶ 8, 53). The SPARC trial's success was crucial, as it "would form the primary basis for an efficacy claim for GPC's NDA for Satraplatin." (Id. ¶ 9). Following the meeting with the FDA, GPC was allowed to proceed with the SPARC trial and the NDA was granted fast track designation. (Id. ¶ 54).

The SPARC trial, which commenced in September 2003 and was completed in December 2005, included 950 patients in 16 countries. (Id. ¶ 10). The "endpoint" used to measure the success of the SPARC trial was progression-free survival ("PFS"). (Id. ¶ 12). "An 'endpoint' for a Phase 3 drug trial is the specific result sought by the applicant which, if shown, would reflect benefits warranting FDA approval." (Id. ¶ 11). For

purposes of this study, PFS was defined as a composite endpoint, consisting of radiographic progression, symptomatic progression, and skeletal related events. (Id. ¶ 104(1)). Defendants' proposed endpoint, PFS, would prove that the drug was effective in delaying the progress of prostate cancer, while the "overall survival" endpoint, regularly used by the FDA, would prove that those using the drug lived longer. (Id. ¶ 13).

On June 9, 2004, GPC filed a Registration Statement with the SEC registering an initial public offering of 7,460,000 bearer shares of GPC in the form of American Depository Shares. (Id. ¶ 60). GPC also filed an Amended Registration Statement and a Prospectus with the SEC on June 10, 2004 and July 1, 2004, respectively. Both registration statements and the prospectus included the following statement:

> We have elected to seek approval under the accelerated approval process for satraplatin. Under the terms of the Special Protocol Assessment, the primary endpoint of the Phase 3 registrational trial for accelerated approval by the FDA will be the time to disease progression [PFS].

(Id. ¶ 60). The Individual Defendants signed the original and amended registration statements. (Id. ¶ 61).

C. GPC's Public Statements and Insider Sales

On December 5, 2005, GPC issued a press release entitled, "GPC Biotech Announces Achievement of Target Enrollment in Satraplatin Phase 3 Registrational Trial (SPARC) for Second-Line Chemotherapy of Hormone Refractory Prostate Cancer." (Id. ¶ 62). Between December 5, 2005 and January 5, 2006, the

Individual Defendants collectively sold 394,795 shares of GPC for a total of 4,325,131 euros. (Id. ¶ 65). They sold their shares pursuant to pre-arranged stock trading plans designed to comply with Rule 10b5-1 of the Securities Exchange Act of 1934, German Law, and GPC's insider trading policy. (Id. ¶ 66). Rule 10b5-1 allows for pre-arranged stock trading plans if corporate insiders are not aware of any material, non-public information. (Id.). Plaintiffs allege that the sales were made pursuant to plans created after the Individual Defendants knew that PFS was an inadequate endpoint, in violation of 10b5-1. (Id.).

In GPC's March 15, 2006 earnings release, Seizinger stated:

> The year 2006 promises to be even more important as we expect to see efficacy data from our Phase 3 registrational trial for satraplatin. Provided these data are positive, our goal is to then complete the NDA filing for marketing approval of satraplatin in the U.S. by the end of this year.

(Id. ¶ 70). Plaintiffs allege that "based on the FDA's clear guidance, . . . [defendants] had no reason to expect Satraplatin would be granted expedited approval based on their current Phase 3 protocol, or that final approval would be obtained." (Id. ¶ 71).

On April 3, 2006, in its annual report, GPC first stated that it had reached an agreement with the FDA to use PFS as the endpoint for the SPARC trial: "[a]s agreed with the FDA and the European Medicines Agency . . . the primary endpoint for the SPARC trial is progression-free survival." (Garbutt Aff. Ex.

1 at 5).[1] The annual report also stated:

> Although satraplatin is eligible for accelerated approval by the FDA, the FDA may not grant an accelerated approval if it concludes that the progression-free survival data and available overall survival data do not demonstrate that satraplatin provides a meaningful therapeutic benefit to patients over existing treatments or that the data are otherwise inadequate to support the granting of an accelerated approval due to weaknesses, inconsistencies or differences in the data with respect to data subsets or subpopulations in the treatment group.

(Id. at 45).

On September 24, 2006, GPC's press release stated that the "study data show that the results for . . . [PFS] are highly statistically significant . . . using the protocol-specified log-rank test." (Compl. ¶ 77). A November 9, 2006 press release explained that the SPARC trial results will "form the basis of our NDA filing, which we expect to submit to the FDA in the next six to twelve weeks, with the goal of filing by the end of this year." (Id. ¶ 78).

Due to the optimistic reporting, the individual defendants again sold large portions of their GPC stock at the inflated prices, totaling proceeds of 17,412,801 euros. (Id. ¶ 79). These sales, like those described above, were made pursuant to pre-arranged stock trading plans allegedly created after the Individual Defendants acquired material inside information. (Id. ¶ 80).

---

[1] I may take judicial notice of documents incorporated by reference into the plaintiffs' pleadings and documents publicly filed with the Securities Exchange Commission. See Kramer v. Time Warner, Inc., 937 F.2d 767, 774 (2d Cir. 1991); In re AES Corp. Sec. Litig., 825 F. Supp. 578, 584 & n.6 (S.D.N.Y. 1993).

On April 16, 2007, GPC issued a press release announcing that the Satraplatin NDA, the final portion of which was submitted to the FDA on February 15, 2007, had been accepted for filing and would be reviewed on an expedited basis. (Id. ¶ 90). On May 15, 2007, Seizinger stated in a press release:

> We are very busy preparing for the possible U.S. launch of satraplatin later this year. With the acceptance of the NDA filing and the assignment of priority review by the FDA, and with senior management of our U.S. marketing and sales organization in place, we have begun to hire the field sales force.

(Id. ¶ 91). GPC's stock price closed at $28.50 per share that day. (Id. ¶ 92).

On June 21, 2007, GPC filed its annual report for the 2006 fiscal year, again referencing an agreement with the FDA on the PFS endpoint: "[b]ased upon an agreement reached with the FDA in 2005, the primary endpoint of the Phase 3 registrational trial for accelerated approval by the FDA will be progression-free survival." (Garbutt Supp. Aff. Ex. 14). The report also stated that the NDA would be reviewed by the Oncological Drugs Advisory Committee ("ODAC") on July 24, 2007. (Id.). "Advisory committees provide the FDA with independent advice from outside experts on issues related to human drugs and other regulated areas. Although the committees provide advice to the agency, final decisions are made by the FDA." (Id.).

GPC's stock price remained high and the individual defendants sold more of their stock as the July 24, 2007 FDA/ODAC assessment date approached. (Id. ¶¶ 97-98).

D. The FDA Report

On July 20, 2007, the FDA issued preliminary comments (the "FDA Briefing Document") in advance of the scheduled meeting. (Compl. ¶ 101; Garbutt Aff. Ex. 8). The document raised five issues, the first dealing with the PFS endpoint:

> **The first issue** is the definition of one of the two primary endpoints, PFS. . . . The FDA has no prior experience with this endpoint. This was clearly communicated to the Applicant during the development phase. FDA will seek ODAC advice on the acceptability of this composite PFS endpoint as the basis of marketing approval.

(Compl. ¶ 101; Garbutt Aff. Ex. 8 at 3) (emphasis in original). GPC's stock price dropped $10.85 over the next two days. (Compl. ¶ 101). The ODAC report, formally issued on July 24, 2007, did not approve GPC's NDA; instead, it recommended waiting for the final results of the SPARC trial, citing "five reasons, including its denunciation of the 'progression-free' endpoint, an endpoint which the panel said it had 'no experience with.'" (Id. ¶ 17; Garbutt Aff. Ex. 9).

As a result, GPC stock plummeted, falling to $13.16 from $31.80 just a few days before, and the company received significant negative press. (Id. ¶¶ 105-12). For example, Forbes.com reported:

> There was a spectacle at the event, watched via a Webcast. It basically came down to a debate between the company and the FDA in which the FDA insisted, fairly strenuously, that it had let the biotech know that its measures of disease progression and pain were not valid.

(Id. ¶ 107).

On July 30, 2007, GPC withdrew its application for expedited approval and, after results showed "that overall survival did not improve for those patients taking satraplatin compared to those taking the placebo, GPC pulled its NDA completely." (Id. ¶¶ 21, 111).

E. Procedural History

On July 26, August 6, and August 23, 2007, three complaints were filed in this Court alleging that defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. In all three cases, plaintiffs sued on behalf of a class of persons who purchased or otherwise acquired GPC securities from December 5, 2005 through July 24, 2007 and who suffered damages as a result. On January 8, 2008, I issued a memorandum decision consolidating the three actions, appointing Axxion as lead plaintiff, and approving Axxion's choice of counsel. See Corwin v. Seizinger, Nos. 07 Civ. 6728, 7016, 7476 (DC), 2008 WL 123846 (S.D.N.Y. Jan. 8, 2008).

On March 12, 2008, Axxion filed its consolidated class action complaint against GPC and the Individual Defendants. Specifically, plaintiffs' complaint alleges violations of Section 10(b) and Rule 10b-5 by GPC, Seizinger, and Scherer. The complaint also alleges that the Individual Defendants violated Sections 20(a) and 20A. On May 15, 2008, defendants moved to dismiss the claims asserted against them.

DISCUSSION

A. Standard on a Motion to Dismiss

On a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief can be granted, the court must accept the factual allegations of the pleading as true and draw all reasonable inferences in favor of the party opposing the motion. Bernheim v. Litt, 79 F.3d 318, 321 (2d Cir. 1996); see Erickson v. Pardus, 127 S. Ct. 2197, 2199 (2007) (per curiam); Bell Atl. Corp. v. Twombly, 127 S. Ct. 1955, 1965 (2007).

In Bell Atlantic Corp., the Supreme Court announced the "retirement" of the oft-quoted "no set of facts" language from Conley v. Gibson, 355 U.S. 41, 45-47 (1957), adopting in its place a "plausibility" requirement. Bell Atl. Corp., 127 S. Ct. at 1969. Bell Atlantic Corp. did not announce a "universal standard of heightened fact pleading, but . . . instead requir[es] a flexible 'plausibility standard,' which obliges a pleader to amplify a claim with some factual allegations in those contexts where such amplification is needed to render the claim plausible." Iqbal v. Hasty, 490 F.3d 143, 157-58 (2d Cir. 2007). The question is whether the pleading alleges "'enough facts to state a claim for relief that is plausible on its face.'" Patane v. Clark, 508 F.3d 106, 111-12 (2d Cir. 2007) (quoting Bell Atl. Corp., 127 S. Ct. at 1974).

In deciding a motion to dismiss, a court may consider the pleadings and attached exhibits, documents incorporated by reference, and matters subject to judicial notice. See Prentice v. Apfel, 11 F. Supp. 2d 420, 424 (S.D.N.Y. 1998) (citing Brass v. Am. Film Techs., Inc., 987 F.2d 142, 150 (2d Cir. 1993)). "'[B]ald contentions, unsupported characterizations, and legal conclusions are not well-pleaded allegations'" and will not defeat the motion. Gavish v. Revlon, Inc., No. 00 Civ. 7291 (SHS), 2004 WL 2210269, at *10 (S.D.N.Y. Sept. 30, 2004) (quoting Citibank, N.A. v. Itochu Int'l, Inc., No. 01 Civ. 6007 (GBD), 2003 WL 1797847, at *1 (S.D.N.Y. Apr. 4, 2003)).

B. Pleading Standard for Securities Actions

Securities fraud allegations are subject to the heightened pleading requirements of Fed. R. Civ. P. 9(b) and the PSLRA. Rule 9(b) requires that, whenever a complaint contains allegations of fraud, the circumstances constituting fraud are to be stated with particularity. See Fed. R. Civ. P. 9(b); see also Chill v. Gen. Elec. Co., 101 F.3d 263, 267 (2d Cir. 1996) (noting that fraudulent statements or conduct must be stated with particularity). "[A] complaint making such allegations must '(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.'" Shields v. Citytrust Bancorp, Inc., 25 F.3d 1124, 1128 (2d Cir. 1994) (quoting Mills v. Polar Molecular Corp., 12

F.3d 1170, 1175 (2d Cir. 1993)). A plaintiff must "set forth the who, what, when, where and how of the alleged fraud." U.S. ex rel. Woods v. Empire Blue Cross & Blue Shield, No. 99 Civ. 4968 (DC), 2002 WL 1905899, at *4 (S.D.N.Y. Aug. 19, 2002) (quotation omitted).

The PSLRA requires securities fraud plaintiffs to "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). While the PSLRA does not require plaintiffs to plead "every single fact upon which their beliefs concerning false or misleading statements are based," it does require the facts alleged to be "sufficient to support a reasonable belief as to the misleading nature of the statement or omission." Novak v. Kasaks, 216 F.3d 300, 313-14 & n.1 (2d Cir. 2000).

"Where plaintiffs contend defendants had access to contrary facts, they must specifically identify the reports or statements containing this information." Id. at 309. To survive a motion to dismiss, plaintiff "needs to specify the internal reports, who prepared them and when, how firm the numbers were or which company officers reviewed them." In re Scholastic Corp. Sec. Litig., 252 F.3d 63, 72 (2d Cir. 2001). For example, an "unsupported general claim of the existence of confidential

company sales reports that revealed [unfavorable figures] is insufficient to survive a motion to dismiss." San Leandro Emergency Med. Group Profit Sharing Plan v. Philip Morris Cos., 75 F.3d 801, 812 (2d Cir. 1996).

Additionally, the Second Circuit does not recognize "fraud by hindsight." Shields, 25 F.3d at 1129. "Mere allegations that statements in one report should have been made in earlier reports do not make out a claim of securities fraud." Stevelman v. Alias Research, Inc., 174 F.3d 79, 84 (2d Cir. 1999) (quotations omitted); see also Novak, 216 F.3d at 309.

C. Section 10(b) and Rule 10b-5 Claims

1. Applicable Law

To state a cause of action under Section 10(b) and Rule 10b-5, plaintiffs must allege that defendants: (1) in connection with a purchase or sale of securities; (2) with scienter; (3) made a material false representation or omitted to disclose material information; (4) upon which plaintiff relied; (5) proximately causing plaintiff to suffer injury. Lentell v. Merrill Lynch & Co., 396 F.3d 161, 172 (2d Cir. 2005); see also Dura Pharm., Inc. v. Broudo, 544 U.S. 336, 341-42 (2005).

a. Materiality

Under Section 10(b) and Rule 10b-5, an omission or misrepresentation must be material -- there must be a substantial likelihood that a reasonably prudent investor would consider it

important in making a decision -- for a duty to disclose to attach. Steinberg v. PRT Group, Inc., 88 F. Supp. 2d 294, 300 (S.D.N.Y. 2000). Materiality is established upon a showing of "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." TSC Indus., Inc. v. Northway, Inc., 426 U.S. 438, 449 (1976); see In re APAC Teleservices, Inc. Sec. Litig., No. 97 Civ. 9145 (BSJ), 1999 WL 1052004, at *9 (S.D.N.Y. Nov. 19, 1999). "It is well-established law that the securities laws do not require disclosure of information that is publicly known." In re Progress Energy, Inc., 371 F. Supp. 2d 548, 552-53 (S.D.N.Y. 2005).

Ordinarily, materiality is a mixed question of law and fact left to the finder of fact to determine. TSC, 426 U.S. at 450. Therefore, "the standard for [dismissing] is high: '[A] complaint may not properly be dismissed pursuant to Rule 12(b)(6) . . . on the ground that the alleged misstatements or omissions are not material unless they are so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance.'" Milman v. Box Hill Sys. Corp., 72 F. Supp. 2d 220, 228 (S.D.N.Y. 1999) (quoting Goldman v. Belden, 754 F.2d 1059, 1067 (2d Cir. 1985) (alterations in original); see also Feinman v. Dean Witter Reynolds, Inc., 84 F.3d 539, 540-41 (2d Cir. 1996).

b. Scienter

To satisfy the Rule 9(b) and PSLRA pleading requirements with respect to scienter, plaintiffs must allege facts giving rise to a "strong inference" of fraudulent intent. Kalnit v. Eichler, 264 F.3d 131, 138 (2d Cir. 2001); see Goplen v. 51job, Inc., 453 F. Supp. 2d 759, 770-71 (S.D.N.Y. 2006).[2] The Supreme Court has held that for the inference of fraudulent intent to qualify as "strong," it must be more than merely plausible or reasonable -- it "must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 127 S. Ct. 2499, 2504-05 (2007).

The requisite intent may be established either by alleging facts (1) showing that defendants had both motive and opportunity to commit fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness. Acito v. IMCERA Group, Inc., 47 F.3d 47, 52 (2d Cir. 1995). With respect to motive, "[g]eneral allegations that the defendants acted in their economic self-interest are not enough," Ganino v. Citizens Utils. Co., 228 F.3d 154, 170 (2d Cir. 2000), and "[m]otives that are generally possessed by most corporate directors and officers do not suffice," Kalnit, 264 F.3d at 139.

---

[2] The Supreme Court recently noted that this circuit's formulation of the pleading demands for scienter has historically been "the most stringent" of all the circuits. See Tellabs, Inc. v. Makor Issues & Rights, Ltd., 127 S. Ct. 2499, 2508 (2007).

As to circumstantial evidence of conscious misbehavior or recklessness, these have been defined by the Second Circuit as "deliberate illegal behavior," and "conduct which is highly unreasonable and which represents an extreme departure from the standards of ordinary care," respectively. Novak, 216 F.3d at 308 (quotations omitted).

c. Loss Causation

To state a Section 10(b) and Rule 10b-5 claim, plaintiffs must allege loss causation. See Lentell, 396 F.3d at 172. Loss causation is "a causal connection between the material misrepresentation and the loss." Dura, 544 U.S. at 342. "[A] plaintiff must allege . . . that the subject of the fraudulent statement or omission was the cause of the actual loss suffered, i.e., that the misstatement or omission concealed something from the market that, when disclosed, negatively affected the value of the security." Lentell, 396 F.3d at 173 (quotation and citation omitted). "[I]f the connection is attenuated, or if the plaintiff fails to demonstrate a causal connection between the content of the alleged misstatements or omissions and the harm actually suffered, a fraud claim will not lie." Id. at 174 (quotations and citations omitted).

"[I]f the loss was caused by an intervening event, like a general fall in the price of [ ] stocks, the chain of causation will not have been established. But such is a matter of proof at trial and not to be decided on a Rule 12(b)(6) motion to

dismiss." Emergent Capital Inv. Mgmt., LLC v. Stonepath Group, Inc., 343 F.3d 189, 197 (2d Cir. 2003). When the plaintiff's loss, however, "coincides with a marketwide phenomenon causing comparable losses to other investors, the prospect that the plaintiff's loss was caused by the fraud decreases." Lentell, 396 F.3d at 174 (quotation omitted).

2. Application

Defendants argue that (1) the complaint's allegations of fraudulent conduct are not pled with the required specificity; (2) Seizinger and Scherer can only be liable for statements they made; (3) the scienter allegations are legally insufficient; and (4) the complaint fails to allege loss causation. For the following reasons, I disagree.

a. Material Misrepresentations and Omissions

Plaintiffs allege that defendants made material misrepresentations in falsely stating that the FDA had agreed to the use of the PFS endpoint for the SPARC trial and material omissions in failing to disclose that the FDA had no experience with the PFS endpoint. Defendants contend that these allegations are conclusory and not sufficiently pled.

First, plaintiffs allege that GPC falsely represented to the public that an agreement had been reached with the FDA that PFS could serve as the primary endpoint for the SPARC trial. GPC's April 3, 2006 annual report stated: "[a]s agreed with the FDA and the European Medicines Agency . . . the primary endpoint for the SPARC trial is progression-free survival." (Garbutt Aff.

Ex. 1 at 5). The June 21, 2007 annual report stated: "[b]ased upon an agreement reached with the FDA in 2005, the primary endpoint of the Phase 3 registrational trial for accelerated approval by the FDA will be progression-free survival." (Garbutt Supp. Aff. Ex. 14).

Plaintiffs contend that these statements were false. The complaint alleges specifically that there was no agreement with the FDA on the use of PFS. Plaintiffs support that allegation by pointing to the FDA's own statement that it had "clearly communicated [its inexperience with the endpoint] to the Applicant during the development phase." (Garbutt Aff. Ex. 8 at 3, Ex. 9 at 7). Although this statement does not in itself show that the FDA did not agree to the PFS endpoint, it certainly makes it plausible that an agreement did not exist. Also, the complaint references the observations of industry reporters who watched the July 24, 2007 ODAC hearing via a webcast and stated that the "FDA insisted, fairly strenuously, that it had let the biotech know that its measures of disease progression and pain were not valid." (Compl. ¶ 107). Another article stated: "GPC had been handling the discussions with the FDA, and it appears the clinical trial design and endpoints for the SPARC study were never signed off on by the agency even though both investors and Spectrum were under the impression they had been." (Id. ¶ 106).[3]

[3] While these articles would seem to be hearsay, they do suggest a good faith basis for plaintiffs' factual assertions.

Second, even assuming the FDA had tentatively agreed to permit the SPARC trial to be conducted using PFS, plaintiffs allege that GPC made material misrepresentations and omissions by issuing overly optimistic press releases that should have disclosed the FDA's inexperience with the PFS endpoint. Both the FDA Briefing Document and the ODAC report contain the FDA's statement that it had told GPC earlier that it was unfamiliar with the PFS endpoint.

Furthermore, the misrepresentations and omissions are material as a reasonable investor could have found the absence of an agreement with the FDA and/or the FDA's lack of experience with the chosen endpoint important in deciding whether to invest in GPC. A "substantial likelihood" exists that GPC's disclosure of the absence of an agreement and/or the FDA's inexperience with the PFS endpoint "would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." TSC Indus., Inc. v. Northway, Inc., 426 U.S. 438, 449 (1976). This is true especially in light of the arguably overly enthusiastic press releases issued by the company stating that the SPARC trial results were "highly statistically significant" and that the company had "already begun to hire the field sales force." (Compl. ¶¶ 77, 91). Because the alleged misrepresentations and omissions were not "so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance," I hold that the complaint sufficiently pleads materiality. Goldman v. Belden, 754 F.2d 1059, 1067 (2nd Cir. 1985).

b. Group Pleading

Defendants next argue that plaintiffs cannot rely on the group pleading doctrine to impose liability upon Seizinger or Scherer for statements they did not personally make.[4] Under the group pleading doctrine, plaintiffs may "rely on a presumption that statements in prospectuses, registration statements, annual reports, press releases, or other group-published information, are the collective work of those individuals with direct involvement in the everyday business of the company." In re Pfizer Inc. Sec. Litig., 584 F. Supp. 2d 621, 637 (S.D.N.Y. 2008) (quoting In re Oxford Health Plans, Inc., 187 F.R.D. 133, 142 (S.D.N.Y. 1999) (internal quotations omitted)). Although the Second Circuit has yet to decide whether the group pleading doctrine has survived the passage of the PSLRA, I join the other courts in this district that have found the doctrine to be "alive and well." In re BISYS Sec. Litig., 397 F. Supp. 2d 430, 439, n.42 (S.D.N.Y. 2005) (collecting cases). See, e.g., In re Refco, Inc. Sec. Litig., 503 F. Supp. 2d 611, 641-42 (S.D.N.Y. 2007) ("[T]here [is no] apparent contradiction between the idea that each defendant's role must be pled with particularity and the fact that corporate officers may work as a group to produce particular document."). Accordingly, defendants Seizinger and Scherer will be held responsible for their own statements as well as the statements made in public filings and press releases.

---

[4] Plaintiffs confirm in their brief that defendants Ewert and Meier are not named in the § 10(b) count.

c. Scienter

Defendants contend that plaintiffs have not alleged facts to show that defendants acted with scienter in stating that an agreement had been reached with the FDA on the PFS endpoint for the SPARC trial or in omitting the FDA's lack of experience with the PFS endpoint. I conclude that scienter has been adequately pled.

According to plaintiffs, defendants represented that the FDA had "agreed" on the PFS endpoint as "the primary endpoint for the SPARC trial" when in fact no such agreement existed. Plaintiffs allege that defendants made positive public statements about the prospects of marketing Satraplatin when they knew that the FDA had "no experience" with PFS as an endpoint, and they knew -- or should have known -- that the FDA's lack of experience with Satraplatin made it unlikely that final approval would be granted. If these allegations, which are plausible, prove to be true, then a reasonable jury could find at a minimum that defendants acted recklessly. See In re Nortel Networks Corp. Sec. Litig., 238 F. Supp. 2d 613, 631 (S.D.N.Y. 2003) (quotations omitted) (quoting Novak v. Kasaks, 216 F.3d 300, 308 (2d Cir. 2000)) ("[S]ecurities fraud claims typically have sufficed to state a claim based on recklessness when they have specifically alleged defendants' knowledge of facts or access to information contradicting their public statements. Under such circumstances, defendants knew or, more importantly, should have known that they were misrepresenting material facts related to the

corporation."). If these allegations are proven, a reasonable fact finder could conclude that defendants' statements in public filings that an agreement did in fact exist and omissions regarding the FDA's concerns with the PFS endpoint were reckless. Thus, plaintiffs have adequately alleged scienter.

d. Loss Causation

The PSLRA provides that plaintiffs "shall have the burden of proving that the act or omission of the defendant . . . caused the loss for which the plaintiff seeks to recover damages." 15 U.S.C. § 78u-4(b)(4). Defendants contend that plaintiffs have not alleged sufficient facts to show that the material misrepresentations and omissions were the proximate cause of the plaintiffs' harm. Defendants' argument is two-fold: (1) GPC stock would have experienced the same losses without the FDA's statements on the PFS endpoint, and (2) because the Committee did not specifically vote on the PFS issue, the losses suffered after the ODAC vote were in no part caused by the FDA's concerns with the endpoint.

i. PFS

Plaintiffs have adequately alleged that PFS was a proximate cause of the losses resulting from the release of the FDA's July 20, 2007 Briefing Document. The complaint alleges that "the stock price dropped $10.85 over the next two trading days, closing at $20.95 on July 23, 2007." (Compl. ¶ 101). These losses were the result of the five issues raised in the

Briefing Document, the first being the FDA's inexperience with the PFS endpoint. Therefore, plaintiffs have sufficiently alleged facts that lead to the inference that some of the loss suffered after the release of the Briefing Document was due to the material misrepresentations and omissions. Compare In re Merrill Lynch, 568 F. Supp. 2d at 365 (S.D.N.Y. 2008) (plaintiffs "attempt to plead loss causation fails because he has not alleged facts that lead to the inference that all, or even some, of his losses are due to the alleged fraud, rather than to intervening events and/or to the disclosure of other information.").

ii. The Vote

Defendants also argue that because the ODAC Committee did not specifically address the definition of the PFS endpoint, no losses suffered after the ODAC vote could be attributed to the misrepresentations and omissions regarding the FDA's concern with the PFS endpoint. First, only one vote was conducted on the final issue presented. Due to time constraints, ODAC did not vote on each specific issue. The comment after the vote was directed, at least in part, at the PFS endpoint: "The committee felt overwhelmingly that without a survival endpoint, Orplatna (satraplatin) reliance on pain progression measured was not possible in this study to the established benefit." Defendants themselves reference the difference between PFS and a survival endpoint: "an endpoint that measured progression of the disease (i.e., PFS), as opposed to some other endpoint, such as overall survival." Thus, the PFS endpoint played some part in the ODAC

vote to reject fast track approval as it was not a survival endpoint.

Industry reports following the meeting focused on the PFS endpoint as well:

> In hindsight, one wonders why GPC sought an accelerated approval using PFS as its end point, when the FDA had already told the company during the regulatory process that it had no previous experience in this area. In our view, the use of an end point not used by the FDA in any approval carries a higher development risk and reflects an ambitious development strategy.
>
> . . .
>
> [A] PFS-based end point -- albeit pursued here in disagreement with the FDA in detail -- is often a less risky end point in oncology studies than meeting a survival advantage.

(Compl. ¶ 112). Thus, plaintiffs have alleged sufficient facts to plead loss causation. The Section 10(b) and Rule 10b-5 claims will go forward.

D. Section 20(a)

The complaint sufficiently alleges control person liability on the Individual Defendants pursuant to Section 20(a).

1. Applicable Law

A plaintiff sufficiently pleads a prima facie case of control person liability by alleging: "(1) a primary violation by the controlled person, (2) control of the primary violator by the defendant, and (3) that the defendant was, in some meaningful sense, a culpable participant in the controlled person's fraud." ATSI Commc'ns, Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 108 (2d

Cir. 2007) (citation omitted). Mere "[a]llegations of control are not averments of fraud and therefore need not be pleaded with particularity." In re Parmalat Sec. Litig., 414 F. Supp. 2d 428, 440 (S.D.N.Y. 2006). The culpable participation factor, however, must be pled "with particular[] facts giving rise to a strong inference that the controlling person knew or should have known that the primary violator, over whom that person had control, was engaging in fraudulent conduct." In re Refco, Inc. Sec. Litig., 503 F. Supp. 2d 611, 660-61 (S.D.N.Y. 2007) (internal citations and quotations omitted).

2. Application

Defendants do not contend that the Individual Defendants were not control persons. Instead, defendants argue that the complaint does not adequately allege culpable participation. The complaint alleges that the Individual Defendants "learned from the FDA that the primary endpoint they selected for the SPARC trial, PFS, was one with which the FDA had no experience and which the FDA would not approve as a primary endpoint." (Compl. ¶ 66). Furthermore, the pre-arranged stock trading plans -- through which the Individual Defendants sold their shares -- were created after the Individual Defendants learned of the non-public information. (Id.). This is sufficient to state a claim of culpable participation.

E. Section 20A Claims

The complaint sufficiently pleads violations of Section 20A by the Individual Defendants.

1. Applicable Law

To plead a claim under Section 20A of the 1934 Act, plaintiffs must allege (1) a predicate violation of the Exchange Act and (2) sufficient facts showing that defendants traded the security at issue contemporaneously with plaintiffs. See In re Take-Two Interactive Sec. Litig., 551 F .Supp. 2d 247, 309 (S.D.N.Y. 2008) (quotation omitted); 15 U.S.C. § 78t-1 ("Any person who violates any provision of this chapter . . . by purchasing or selling a security while in possession of material, nonpublic information shall be liable . . . to any person who, contemporaneously with the purchase or sale of securities that is the subject of such violation, has purchased . . . or sold . . . securities of the same class.").

2. Application

Defendants argue that the Section 20A claims should be dismissed because the trades were not contemporaneous. Defendants would have this Court hold that the trades must take place on the same day to satisfy the contemporaneous requirement. (Def. Mem. at 33). This Court will not adopt such a restricted holding. Although the Second Circuit has yet to address the contemporaneous requirement, other courts in this district have concluded that trades within periods of up to six days are contemporaneous. See, e.g., In re Pfizer Inc. Sec. Litig., 584 F. Supp. 2d 621, 642 (S.D.N.Y. 2008) (citing cases) (The Court "cannot say as a matter of law that trades made within less than a week are insufficiently contemporaneous."). Moreover, I find

that the term "contemporaneous" in the context of trades surely does not imply such a short period of time as to restrict the period to one single day.

Plaintiffs purchased securities on June 11, June 12, and July 23, 2007. (Compl. Exs. A, B). Plaintiffs, therefore, have alleged trades within six days of sales by Maier (June 12, 2007), Ewert (June 18, 2007), and Seizinger (July 19, 2007), and ten days by Scherer (July 13, 2007). Sales within six days or even ten days may be "contemporaneous," in the context here, and this prong of the motion is denied, without prejudice to renewal in a summary judgment motion following the close of discovery. (Compl. ¶¶ 99, 138, Exs. A, B). The Section 20A claim is sufficiently pled.

CONCLUSION

For the foregoing reasons, defendants' motion to dismiss is denied. The parties shall attend a pre-trial conference on March 13, 2009 at 10:30 am.

SO ORDERED.

Dated: New York, New York
February 13, 2009

DENNY CHIN
United States District Judge